

HAND SANITIZER- alcohol gel

Webb Business Promotions, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Anti-Bacterial Hand Sanitizer Gel

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help decrease bacteria on the skin.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Squeeze enough product on hands to cover all surfaces. Rub hands together until dry.

Other information

- Store between 20C (68-77F)
- May discolor fabrics

Inactive ingredients

Water, Propylene Glycol, Carbomer, Tocopherol, Aloe Vera

Package Label - Principal Display Panel

Drug Facts	Antibacterial Hand Sanitizer Gel
Active Ingredients Ethyl Alcohol 75%	Purpose Antiseptic
Uses: Hand Sanitizer to help decrease bacteria on the skin.	
Warnings: For external use only. Flammable. Keep away from heat or flame. Keep out of eyes, ears & mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask doctor if redness or irritation develop and persist for more than 72 hours. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Do not use on children less than 2 months of age. Do not use on open skin wounds.	
Directions: Squeeze enough product on hands to cover all surfaces. Rub hands together until dry.	
Other Information: Store at 20° C (68° to 77° F). May discolor fabrics.	
Inactive Ingredients: Deionized Water, Propylene Glycol, Carbomer, Fragrance, Tocopherol, Aloe Vera.	
Webb Egan, MN 55121	MADE IN USA 2 FL OZ. (60ML)

240 mL NDC: 70445-414-18

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70445-414
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mL in 100 mL
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70445-414-37	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/10/2020	
2	NDC:70445-414-18	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2020	
3	NDC:70445-414-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Webb Business Promotions, Inc (154445647)**Registrant** - Webb Business Promotions, Inc (154445647)**Establishment**

Name	Address	ID/FEI	Business Operations
Webb Business Promotions, Inc		154445647	manufacture(70445-414)

Revised: 1/2022

Webb Business Promotions, Inc